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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,547	11/12/2003	Linda S. Powers	13368.0001 (DIV. I)	6904
7590 12/23/2004			EXAMINER	
K. S. Cornaby Suite 1500 170 South Main Street Salt Lake City, UT 84101-1644			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,547

Applicant(s)

POWERS ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 24,25 and 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23,26 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 22062004.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed November 16, 2004, wherein amendments to the specification and claims have been entered.
2. Claims 21-37 and 53 are pending.
3. Claims 24, 25, and 27-37 are withdrawn.
4. Claims 21-23, 26, and 53 are currently amended.
5. Claims 1-20, 38-52, and 54-83 are canceled.

Withdrawn Rejections

1. Applicant's arguments and amendments, see pages 15-18, filed November 16, 2004, with respect to claims 21-23, 26, and 53 have been fully considered and are persuasive. The rejections under 35 U.S.C. 112, first and second paragraph of claims 21-23, 26, and 53 have been withdrawn.

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Groups a-b each comprise a separate invention under 35 U. S.C. §121. These groups represent the identification method wherein the biological analyte to be identified is:

- a. proteinaceous toxins
- b. cytosolic proteins

Groups i-iii each comprise a separate invention under 35 U.S.C. §121. These groups represent the identification method wherein the ligand specific for the analyte of interest is:

- i. peptide specific to a proteinaceous toxin
- ii. peptide specific to a proteinaceous hormone
- iii. peptide specific to a cytosolic protein

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Groups 1-7 each comprise a separate invention under 35 U.S.C. §121. These groups represent the identification method wherein the method of detection of the capture analyte is:

- (1) Through detecting the intrinsic fluorescence of the protein
- (2) Through fluorescence of a reactive dye conjugate
- (3) Through detecting the radioactivity of a reactive compound
- (4) Through luminescence of a reactive dye conjugate
- (5) Through phosphorescence of a reactive dye conjugate
- (6) Through optical absorbance of a reactive dye conjugate
- (7) Through fluorescent quenching of the tethered ligand surface.

1. The claims are deemed to correspond to the species listed above in the following manner:

The species for the biological analyte are drawn to claims 22.

The species for the ligand are drawn to the following claims: 23 and 53.

The species for the detection of the capture analyte are drawn to the following claims: 26 and 53.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the three groups listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Currently amended claim 53 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim contains non-elected methods of interrogation and non-elected protein analyte.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 53, parts (ii)-(vii) and parts (ii)-(iii) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 21-23, 26 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al. (WO 98/49557) in view of Hudson et al. (US 5,576,220).

Powers et al. teach a method for identification of a biological analyte comprising: exposing a solution containing the analyte to a ligand specific for the analyte of interest that has been bound directly to a photostable linker (pg. 25, first paragraph); and interrogation of the ligand-tethered substrate surface for analyte binding by detection of the bound analyte (pg. 25, first paragraph). Powers et al. do not specifically teach the linker covalently tethered to a substrate surface or having a length of at least 6 Å. However, the tethers for proteinaceous

toxins taught in pages 19-23 of Powers et al. are identical to the tethers taught for proteinaceous toxins in pages 19-22 of the instant specification. Therefore, one of ordinary skill in the art would know that because the tethers are identical, they would produce covalent bonds with the substrate and have a length of at least 6 Å. Powers et al. fail to teach separating the bound analyte from the non-binding components of the solution.

Hudson et al. teach separating bound analyte from non-binding components of a solution containing analyte, by physical separation of the substrate surface from the sample by centrifugation (col. 18, lines 1-24) or washing (col. 14, lines 37-42) in order to remove weak binding pairs.

Therefore, it would have been obvious to one having ordinary skill in the art to include in the method of Powers et al., a physical separation of the bound analyte from non-binding components as taught by Hudson et al., in order to prevent signal removal by extensive washing.

Powers et al. teach the biological analyte being proteinaceous toxins (pg. 1, 1st paragraph and pg. 10, 2nd paragraph) and the peptide specific for a proteinaceous toxin (pg. 13-14; pg. 25, 1st paragraph). Powers et al. also teach the detection of the captured analyte accomplished through an intrinsic fluorescence of the tryptophan and/or tyrosine residues present in the captured protein (pg. 18, 1st paragraph; pg. 32, 1st paragraph) where the intrinsic fluorescence is detected between 300 and 400 nm (pg. 32, Table 2, row 3, column 3) upon excitation by ultraviolet light (pg. 32, 1st sentence) between 200 and 300 nm (pg. 32, Table 3, row 3, column 2).

Hudson et al. teach a peptide ligand containing from two to about 100 amino acids (col. 7, line 64 - col. 8, line 11), which reads on the recited range of three to twenty amino acids.

Response to Arguments

2. Applicant's arguments, see pages 18-25, filed November 16, 2004, with respect to the rejection(s) of claim(s) 21 and 53 under 35 U.S.C. 102(b) and claims 22, 23, and 26 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Powers et al. (WO 98/49557) in view of Hudson et al. (US 5,576,220).

3. Applicant's arguments with respect to claims 21-23, 26, and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. No claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



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12/20/04